Ansell

DEC 1 9 2003

K033076

510(k) SUMMARY

Submitted by: Ansell Healthcare Inc.
1635 Industrial Road
Dothan, AL 36303
USA

Contact Person: Lon D. McIlvain
Quality Assurance/Regulatory Manager
Telephone: 334-794-4231 or 334-615-2562
Fax: 334-615-2568

Date Prepared: September 25, 2003

Proprietary Name: LifeStyles® Liquid Personal Lubricant

Common Name: Personal Lubricant

Classification Name: Condom (21 CFR §884.5300) Product Code 85HIS

Predicate Device: Astroglide® Personal Lubricant (K935299)
K-Y® Liquid Personal Lubricant (K955648)

Description of the Device:
LifeStyles® Liquid Personal Lubricant is a non-sterile, water-based personal lubricant designed to supplement the body's natural lubrication fluids. The formula is a non-greasy, non-sticky, non-staining and non-irritating gel-like liquid that is compatible with latex condoms in laboratory testing. LifeStyles® Liquid Personal Lubricant is available over-the-counter in three formulas:

LifeStyles® Liquid Personal Lubricant Long Lasting
LifeStyles® Liquid Personal Lubricant Aloe & Vitamin E
LifeStyles® Liquid Personal Lubricant Strawberry

The product is packaged in a plastic tube with a flip-top cap or in an aluminum foil/plastic film laminate sachet.

Intended Use of the Device:
Patient lubricants are devices intended to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. If used as an accessory to a condom, patient lubricants are deemed Class II Medical Devices.

LifeStyles® Liquid Personal Lubricant is principally intended as personal lubricant to supplement the body's natural lubrication fluids, to moisturize, and to enhance the comfort and ease of intimate sexual activity with or without a latex condom.

Technological Characteristics:
The LifeStyles® Liquid Personal Lubricant formulations contain ingredients that are substantially the same as those used to manufacture the predicate devices. The strawberry fragrance used in the strawberry formulation contains standard ingredients commonly used in cosmetic applications as well as in drug flavors. The D&C and FD&C red colors are approved for use in drug and cosmetic applications. Aloe and Vitamin E are approved for use and commonly used in cosmetic applications.

The table below compares the technological characteristics of LifeStyles® Liquid Personal Lubricant to the predicate devices, K-Y® Liquid Personal Lubricant and Astroglide®.

Feature	LifeStyles® Liquid Personal Lubricant	K-Y® Liquid Personal Lubricant	Astroglide®
Manufacturer	Ansell Healthcare Inc.	McNeil-PPC, Inc.	BioFilm Inc.
Contains dionized water	Yes	No	No
Contains purified water	No	Yes	Yes
Contains glycerine	Yes	Yes	Yes
Contains Cellulose thickeners	Yes	Yes	No
Contains Methylparaben	Yes	Yes	Yes
Contains Propylparaben	Yes	No	Yes
Labeled water soluble	Yes	Yes	Yes
Labeled non-staining	Yes	Yes	Yes
Labeled condom compatible	Yes	Yes	Yes
Labeled alcohol and fragrance free	No	No	No
Container material	Plastic or Foil/Plastic Film Laminate	Plastic	Plastic
Sterile	No	No	No

LifeStyles® Liquid Personal Lubricant was tested by independent laboratories for condom compatibility, biocompatibility, and preservative effectiveness. Independent testing has also demonstrated that LifeStyles® Liquid Personal Lubricant does not affect the in-vitro spermicidal activity of condoms lubricated with spermicide (Nonoynol-9).

Conclusion
LifeStyles® Liquid Personal Lubricant is substantially equivalent to its predicate devices, K-Y® Liquid Personal Lubricant and Astroglide®. All of these products have the same intended use and similar technological characteristics. Therefore, no new safety and effectiveness issues are expected to be raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Ms. Cynthia A. Ingram
Regulatory Affairs Administrator
Ansell Healthcare, Inc.
1635 Industrial Road
Dothan, Alabama 36303

Re: K033076
Trade/Device Name: LifeStyles® Liquid Personal Lubricant
Long Lasting, Aloe & Vitamin E, and Strawberry
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: September 25, 2003
Received: September 29, 2003

Dear Ms. Ingram:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K033076**

Device Name: **LifeStyles® Liquid Personal Lubricant**

Indications For Use:

LifeStyles® Liquid Personal Lubricant is principally intended as personal lubricant to supplement the body's natural lubrication fluids, to moisturize, and to enhance the comfort and ease of intimate sexual activity with or without a latex condom.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033076